

exceeds 50 percent protection, the Unknown is satisfactory without additional testing.

(10) If the RP is less than the minimum required in paragraph (c)(7) of this section, the serial may be retested by conducting two independent replicate tests in a manner identical to the initial test. The average of the RP values obtained in the retests shall be determined. If the average RP is less than the required minimum, the serial is unsatisfactory. If the average RP obtained in the retests is equal to or greater than the required minimum, the following shall apply:

(i) If the RP obtained in the original test is one-third or less than the average RP obtained in the retests, the initial RP may be considered a result of test system error and the serial is satisfactory.

(ii) If the RP value obtained in the original test is more than one-third the average RP obtained in the retests, a new average shall be determined using the RP values obtained in all tests. If the new average is less than the minimum required in paragraph (c)(7) of this section, the serial is unsatisfactory.

[43 FR 25077, June 9, 1978, as amended at 48 FR 31009, July 6, 1983. Redesignated at 55 FR 35562, Aug. 31, 1990, as amended at 56 FR 66785, Dec. 26, 1991]

KILLED VIRUS VACCINES

§ 113.200 General requirements for killed virus vaccines.

When prescribed in an applicable Standard Requirement or in the filed Outline of Production, a killed virus vaccine shall meet the applicable requirements in this section.

(a) *Killing Agent.* The vaccine virus shall be killed (inactivated) by an appropriate agent. The procedure involved may be referred to as inactivation. Suitable tests to assure complete inactivation shall be written into the filed Outline of Production.

(b) *Cell Culture Requirements.* If cell cultures are used in the preparation of the vaccine, primary cells shall meet the requirements in § 113.51 and cell lines shall meet the requirements in § 113.52.

(c) *Purity Tests.* (1) *Bacteria and fungi.* Final container samples of completed product from each serial shall be tested as prescribed in § 113.26.

(2) *Avian Origin Vaccine.* Bulk pooled material or final container samples from each serial shall also be tested for:

(i) *Salmonella* contamination as prescribed in § 113.30; and

(ii) *Lymphoid leukosis virus* contamination as prescribed in § 113.31; and

(iii) *Hemagglutinating viruses* as prescribed in § 113.34.

(3) *Mycoplasma.* If the licensee cannot demonstrate that the agent used to kill the vaccine virus would also kill mycoplasma, each serial of the vaccine shall be tested for mycoplasma as prescribed in § 113.28, prior to adding the killing agent. Material found to contain mycoplasma is unsatisfactory for use.

(4) *Extraneous viruses.* Each lot of Master Seed Virus used to prepare killed virus vaccine recommended for animals other than poultry shall meet the requirements for extraneous viruses as prescribed in § 113.55.

(d) *Safety Tests.* Final container samples of completed product from each serial shall be tested for safety in guinea pigs as prescribed in § 113.38 and for safety in mice as prescribed in § 113.33: *Provided*, That, vaccines recommended for use only in poultry are exempt from this requirement.

(e) *Viricidal Activity Test.* Only serials tested for viricidal activity in accordance with the test provided in § 113.35 and found satisfactory by such test shall be packaged as diluent for desiccated fractions in combination packages.

(f) *Formaldehyde content.* If formaldehyde is used as the killing agent, the residual free formaldehyde content shall not exceed the equivalent of 0.2 percent formaldehyde solution (740 parts per million formaldehyde).

[39 FR 27428, July 29, 1974, as amended at 40 FR 23989, June 4, 1975; 43 FR 49528, Oct. 24, 1978. Redesignated at 55 FR 35562, Aug. 31, 1990]

§ 113.201 Canine Distemper Vaccine, Killed Virus.

Canine Distemper Vaccine, Killed Virus, shall be prepared from virus-bearing cell culture fluids. Only Master